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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/734,721	12/11/2003	Michael Patane	CASM122095	1968

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EXAMINER	
KISHORE, GOLLAMUDI S	

ART UNIT	PAPER NUMBER
1612	

MAIL DATE	DELIVERY MODE
04/08/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/734,721	PATANE, MICHAEL	
	Examiner	Art Unit	
	Gollamudi S. Kishore, Ph.D	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 September 2007*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) *21-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The response dated 9-21-07 is acknowledged.

Upon consideration, the previous rejections are withdrawn. The following are the new rejections.

Claims included in the prosecution are 1-20. Claims 21-30 remain withdrawn.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1- 5, 7-12 and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stamatatos (Biochemistry, 1988) or Perrie (Vaccine, 2001) or Anzai (J. Biochem, 1993) (all are of record) individually or combination, in further combination with WO 85/04880 of record.

Stamatatos teaches that cationic lipid vesicles interact with biological membranes. The vesicles taught by Stamatatos include PE, PC and DOTAP in a molar ratio of 40:40:20 mole percent (abstract, pages 3920-3921 and discussion). Stamatatos differs from instant composition with respect to the amounts of PE and DPTAP. Stamatatos also lacks the inclusion of cholesterol.

Perrie teaches liposomal formulations containing DNA. The liposomes contain PC, PE and DOTAP in mole percentages of 57, 28 and 14 (abstract and Table 1). Perrie differs from instant composition with respect to the amounts of PE and PC. Stamatatos also lacks the inclusion of cholesterol.

Anzai similar teaches that liposomes containing DPTAP, PE and PC in molar ratios of 20:56:24 fuse with bilayer membranes (abstract and Results and Discussion). Anzai differs from instant composition with respect to the amounts of PE and PC. Anzai also lacks the inclusion of cholesterol.

WO 85 while disclosing acid induced liposome fusion method teaches that the presence of phosphatidylethanolamine in the liposomes greatly enhances the fusion. WO also teaches that cholesterol (40 %) greatly decreases the leakage without impairing fusion. The fatty acid taught is oleic acid. The compositions are for the delivery of molecules such as DNA. The molar percentages for PE: cholesterol: PC as calculated from the values in Table II are 40: 40: 20 (abstract, examples and claims).

It would have been obvious to one of ordinary skill in the art to include cholesterol and vary its amounts in Stamatatos, Perrie or Anzai since it greatly decreases the leakage without inhibiting the fusion even at 40 % as taught by WO. Similarly to vary the amounts of the components would have been obvious to one of ordinary skill in the art to obtain the best possible results since the references show that they can be varied.

4. Claim 1-12 and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stamatatos (Biochemistry, 1988) or Perrie (Vaccine, 2001) or Anzai (J. Biochem,

1993) (all are of record) individually or combination, in further combination with WO 85/04880 of record. as set forth above, further in view of Heath (5,902,802).

The teachings of Stamatatos, Perrie, Anzai and WO have been discussed above. What is lacking in these references is the teaching of the use of ergo sterol instead of cholesterol.

Heath while disclosing liposomes containing cationic lipids teaches that either ergo sterol or cholesterol could be used in the liposomes in combination with the cationic lipids. The sterol amounts suggested are 0-67 mole percent (col. 6, lines 43-55).

The use of ergo sterol instead of cholesterol in the liposomal compositions would have been obvious to one of ordinary skill in the art since Heath teaches that ergo sterol could be used instead of cholesterol. To lower the amounts of cholesterol would have been obvious to one of ordinary skill in the art since Heath teaches that its amounts could be varied from 0 to 67 mole percent.

5. Claim 13-15 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stamatatos (Biochemistry, 1988) or Perrie (Vaccine, 2001) or Anzai (J. Biochem, 1993) (all are of record) individually or combination, in further combination with WO 85/04880 of record or these references further in view of Heath (5,902,802) as set forth above, further in view of Kapeller-Libermann (2002-0081633).

The teachings of Stamatatos, Perrie, Anzai, WO and Heath have been discussed above. What is lacking in these references is the teaching of encapsulation of a phosphodiesterase.

Kapeller-Libermann while disclosing method of using a cyclic nucleotide phosphodiesterase teaches that delivery systems such as liposomes can be used to deliver phosphodiesterase to cells in vitro as well as in vivo (abstract, 0334 and 0343).

It would have been obvious to one of ordinary skill in the art to encapsulate a phosphodiesterase in the liposomes of Torchillin, WO and Heath with a reasonable expectation of success since Kapeller-Libermann teaches that this enzyme can be encapsulated within liposomes for the delivery to cells in vitro.

6. Claim 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stamatatos (Biochemistry, 1988) or Perrie (Vaccine, 2001) or Anzai (J. Biochem, 1993) (all are of record) individually or combination, in further combination with WO 85/04880 of record or these references further in view of Heath (5,902,802) as set forth above, further in view of Conklin (2002-0156259).

The teachings of Stamatatos, Perrie, Anzai, WO and Heath have been discussed above. What is lacking in these references is the teaching of encapsulation of a deaminase.

Conklin while disclosing method of using deaminases teaches that delivery systems such as liposomes can be used to deliver a deaminase (abstract, 0287-0292).

It would have been obvious to one of ordinary skill in the art to encapsulate a deaminase in the liposomes of Torchillin, WO and Heath with a reasonable expectation of success since Conklin teaches that this enzyme can be encapsulated within liposomes for the delivery to cells in vitro.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S. Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Krass Frederick can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gollamudi S Kishore, Ph.D/
Primary Examiner, Art Unit 1612

GSK